Remarks

Reconsideration of this Application is respectfully requested.

As explained in the Brief on Appeal Under 37 C.F.R. § 41.37 filed February 10, 2009, the present listing of the claims is based on the prior listing of the claims in the Amendment and Reply Under 37 C.F.R. § 1.116 filed September 10, 2008 which was entered for the purposes of appeal in the Advisory Action dated November 14, 2008.

Upon entry of the foregoing amendments, claims 1 and 4-17 are pending in the application, with claim 1 being the sole independent claim. Claims 2 and 3 were previously canceled without prejudice to or disclaimer of the subject matter therein. The Office Action Summary dated June 4, 2009 indicates that claims 6, 7 and 10-12 are withdrawn from consideration. However, the Office Action Summary does not reflect the status of claim 13. For the purposes of the present Amendment and Reply, Applicants will assume that the status of claim 13 is "withdrawn," as indicated in the Advisory Action dated November 14, 2008. However, Applicants respectfully request that the Examiner clarify the status of claim 13.

The title is sought to be amended in view of the present claims. Claims 1, 16 and 17 are sought to be amended to correct obvious typographical errors. As such, these changes are believed to introduce no new matter, and their entry is respectfully requested. In addition, support for the amendment of claim 16 can be found, for example, at paragraph [0046] of the specification as filed December 15, 2003.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider the outstanding rejection and that it be withdrawn.

I. Telephone Conversation With The Examiner

Applicants thank the Examiner for reopening examination of the present application following the Brief on Appeal Under 37 C.F.R. § 41.37 filed February 10, 2009 and for withdrawing the obviousness rejection in the final Office Action dated July 10, 2008. Applicants also thank the Examiner for discussing the present application with Applicants' undersigned representative during a telephone conversation on June 24, 2009. During the telephone conversation, Applicants' representative discussed the claims and present Office Action with the Examiner. Applicants submit the following comments as discussed with the Examiner.

As explained in the Brief on Appeal, the Examiner requested an election of a single species of 5-lipoxygenase inhibitor in the Office Action mailed April 9, 2007. Applicants provisionally elected the "phenyl pyrazoline derivatives" species with traverse in the Reply to Requirement for Election of Species filed April 30, 2007. In the Office Action dated July 26, 2007, the Examiner withdrew claims 6, 7, and 10-13 and examined the elected species of phenyl pyrazoline derivatives. As such, Applicants addressed claims 1, 4, 5, 8, 9 and 14-17 in the Brief on Appeal to the extent that the Examiner had examined the elected species, although some of claims 1, 4, 5, 8, 9 and 14-17 included other species. In the present Office Action, the Examiner has withdrawn the final rejection of claims 1, 4, 5, 8, 9 and 14-17 as obvious under 35 U.S.C. § 103(a) and issued the present rejection of claims 1, 4, 5, 8, 9, and 14-17 under 35 U.S.C. § 112, first

paragraph, for lack of enablement. In the Office Action, the Examiner comments on the enablement for "the use of all 5-lipoxygenase inhibitors." *See, e.g.*, Office Action at pages 2 and 3. As such, it appears that the Examiner has examined the claims with regard to the larger genus of "5-lipoxygenase inhibitors," rather than the elected "phenyl pyrazoline derivatives" species.

Applicants respectfully request that the Examiner clarify the scope of the claimed subject matter being examined in the present Office Action. In view of the apparent examination of the larger genus of 5-lipoxygenase inhibitors by the Examiner, Applicants request that the Examiner inform Applicants whether the "phenyl pyrazoline derivatives" species is allowable and whether additional species have been rejoined for examination. *See, e.g.*, M.P.E.P. §§ 821.04 and 821.04(b). Also, as discussed during the telephone conversation, Applicants respectfully request that the Examiner consider the enablement of the present claims on an individual basis, and provide below comments with regard to the full scope of the claims.

II. Rejection Under 35 U.S.C. § 112, First Paragraph - Enablement

The Examiner rejected claims 1, 4, 5, 8, 9 and 14-17 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. *See* Office Action at pages 2-4. In particular, the Examiner alleged that the specification, "while being enabling for the use of one phenyl pyrazoline derivative for lowering serum triglyceride, does not reasonably provide enablement for the use of all 5-lipoxygenase inhibitors for lowering serum triglyceride." Office Action at page 2. Applicants respectfully disagree.

A. Legal Principles

In order to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, the claimed invention must be enabled so that a person of skill in the art can make and use the invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Some experimentation, even a considerable amount, is not "undue" if, for example, it is merely routine. *Id.* In addition, an Applicant is not limited to the confines of the specification to provide the necessary information to enable an invention. *See In re Howarth*, 654 F.2d 103, 105-6 (CCPA 1981). Further, an Applicant need not supply information that is well known in the art. *See, e.g., Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1366 (Fed. Cir. 1997); *Howarth*, 654 F.2d at 105-6; *In re Brebner*, 455 F.2d 1402 (CCPA 1972). For at least the following reasons, Applicants assert that it would require no more than routine experimentation for a skilled artisan to practice the full scope of the present claims in view of the teachings in the specification and the knowledge available in the art. Thus, the enablement requirement of 35 U.S.C. § 112, first paragraph, is fully satisfied for the present claims.

B. One of ordinary skill in the art could practice the full range of methods encompassed by the present claims using only routine methods and experimentation.

In explaining the enablement rejection, the Examiner alleged that the specification does not reasonably provide enablement for the use of all 5-lipoxygenase inhibitors for lowering serum triglycerides. *See, e.g.*, Office Action at page 3. Applicants assert that the specification fully enables the present claims in view of the disclosure in the specification and the knowledge of one of ordinary skill in the art.

First, the specification provides general guidance for the use of 5-lipoxygenase inhibitors for lowering serum triglycerides. In particular, the specification provides that anti-inflammatory compounds may prove useful in the treatment or prevention of metabolic syndrome, diabetes or related metabolic diseases, as well as related complications such as hyperlipidemia and elevated serum triglyceride levels. *See, e.g.*, paragraphs [0014] and [0015]. At the time the present specification was filed, there were numerous anti-inflammatory targets in the art; however, the art did not teach the use of 5-lipoxygenase inhibitors as a class of anti-inflammatory agents that would be useful in the treatment of hyperlipidemia or elevated serum triglycerides. *See, e.g.*, paragraphs [0014], [0015] and [0037]. Moreover, it was known in the art that agents useful in the treatment of hyperlipidemia, such as masoprocol and curcumin, are poorly bioavailable agents and thus, must be administered in prohibitive and possibly toxic concentrations. *See, e.g.*, paragraphs [0007] and [0014]. As such, the present inventors fulfilled a need in the art for, and the specification provides, a new means to reduce elevated serum triglyceride levels using 5-lipoxygenase inhibitors.

Second, the specification provides detailed description for the 5-lipoxygenase inhibitor group. Specifically, the specification provides that the enzyme 5-lipoxygenase coverts arachidonic acid to 5-hydroperoxyeicosatetraenoic acid (5-HPETE) as the first step in the metabolic pathway yielding 5-hydroxyeicosatetraenoic acid (5-HETE) and leukotrienes. *See, e.g.*, paragraph [0032]. The term "5-lipoxygenase inhibitor" is defined in paragraph [0032] as compounds that interfere with this metabolic pathway. According to the specification, such compounds may interfere through a variety of mechanisms, including blocking the association of the 5-lipoxygenase enzyme with membranes,

inhibiting the translocation of the enzyme by proteins such as 5-lipoxygenase-activating protein (FLAP), or blocking the enzyme activity directly by acting as a substrate or depriving the enzyme of necessary cofactors. *See, e.g.*, paragraph [0032].

Third, numerous specific examples of 5-lipoxygenase inhibitors are provided in the specification as well as methods to make and test such compounds. *See, e.g.*, paragraphs [0037]-[0044]. For example, paragraph [0017] provides that 5-lipoxygenase inhibitors useful in the claimed methods include acetohydroxamic acid derivatives, phenyl pyrazoline derivatives, 2-(12-hydroxydodeca-5,10-diynyl)-3,5,6-triemthyl-1,4-benzoquinone derivatives, and 3-[1-(4-chlorobenzyl)-3-t-butyl-thio-5-isopropyllindol-2-yl]-2,2-dimethyl propanoic acid derivatives. Other examples of 5-lipoxygenase inhibitors provided in the specification include:

(i) 4,5-dihydro-1-(3-(trifluoromethyl)phenyl)-1H-pyrazol-3-amine (BW 755c) (*see, e.g.*, paragraph [0018]);

(ii) N-(3-phenoxycinnamyl)acetohydroxamic acid (BW 4AC) (*see, e.g.*, paragraph [0019]);

(iii) 2-(12-hydroxydodeca-5,10-diynyl)-3,5,6-trimethyl-1,4-benzoquinone (AA861) (*see, e.g.*, paragraph [0020]);

(iv) 3-[1-(4-chlorobenzyl)-3-t-butyl-thio-5-isopropylindol-2-yl]-2,2-dimethyl propanoic acid (MK886) (*see, e.g.*, paragraph [0021]); and

(v) specified MK886 derivatives (*see, e.g.*, paragraph [0043]).

Therefore, the specification provides detailed description for the members of the 5-lipoxygenase inhibitor group as well as numerous specific examples of 5-lipoxygenase inhibitors and methods to make and test such compounds.

Fourth, the specification provides detailed methods for testing, and experimental results showing, the *in vivo* efficacy of 5-lipoxygenase inhibitors in an animal model of hypertriglyceridemia. *See, e.g.*, Examples 1 and 2. In particular, the specification provides a diet-induced animal model of hypertriglyceridemia using rats fed with a high-fructose diet and treated with 5-lipoxygenase inhibitors. Serum triglyceride levels are then analyzed in the treated rats, for example, using diagnostic kits. Figure 1 shows treatment with the 5-lipoxygenase inhibitor BW 755c resulted in a significant decrease in serum triglycerides in rats fed a high fructose diet. *See, e.g.,* Figure 1, "BW-755c 100 mg/kg bid," Figure 2B, top panel "BW-755c-5," Tables 1 and 2, page 24 and paragraph [0074] of the specification.

Fifth, the specification provides detailed support regarding pharmaceutical dosage forms useful in the claimed methods. *See, e.g.*, paragraphs [0051]-[0069]. For example, the specification provides description related to pharmaceutically effective dosages of 5-lipoxygenase inhibitors (*see, e.g.*, paragraph [0052]); pharmaceutically acceptable carriers useful in pharmaceutical compositions comprising 5-lipoxygenase inhibitors (*see, e.g.*, paragraphs [0054]-[0056]); and specific dosage forms and administration routes for administration of 5-lipoxygenase inhibitors (*see, e.g.*, paragraphs [0057] and [0059]).

In view of the detailed description regarding the use of 5-lipoxygenase inhibitors in the treatment of hyperlipidemia, the numerous examples of 5-lipoxygenase inhibitors, and the experimental methods for testing and showing the *in vivo* efficacy of 5-lipoxygenase inhibitors in the treatment of hyperlipidemia, a person of ordinary skill in the art could practice the subject matter of the present claims without undue

experimentation. Undue experimentation does not mean "no" experimentation, only that it be reasonable. *See, e.g., In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). For at least the above reasons, a person of ordinary skill in the art at the time of filing would have possessed the knowledge and skills necessary to make and use the subject matter of the present claims. Thus, any experimentation required to practice the claimed methods is reasonable, not undue.

C. The specification provides a correlation between the inhibition of the 5-lipoxygenase pathway and the treatment of elevated serum triglycerides.

The Examiner, in explaining the enablement rejection, alleged that no correlation has been established between the inhibition of the 5-lipoxygenase pathway and treating elevated serum triglycerides. *See* Office Action at pages 3. Applicants respectfully disagree.

As detailed above, the specification provides:

(i) the use of 5-lipoxygenase inhibitors in the treatment of hyperlipidemia and elevated serum triglycerides (*see, e.g.*, paragraphs [0014], [0015] and [0037]);

(ii) numerous examples of 5-lipoxygenase inhibitors and methods to make and test such compounds (*see, e.g.*, paragraphs [0037]-[0044]); and

(iii) experimental methods for testing and experimental results showing *in vivo* efficacy of 5-lipoxygenase inhibitors in animal models of hypertriglyceridemia (*see, e.g.*, Figures 1 and 2).

In view of at least this disclosure, Applicants assert that the specification clearly correlates the inhibition of the 5-lipoxygenase pathway and the treatment of elevated serum triglycerides.

At page 3 of the Office Action, the Examiner cited *In re Dreshfield*, 110 F.2d 235 (CCPA 1940), for the proposition that a specification providing chemicals and chemical compounds which differ radically in their properties must either provide a sufficient number of members of the group, or that the chemicals and chemical compounds are capable of accomplishing the desired results. Applicants submit that the passage cited by the Examiner from *Dreshfield* is not applicable to an enablement rejection, particularly in view of the decision by the Board of Patent Appeals and Interferences in *Ex parte Reese*, 40 U.S.P.Q.2d (BNA) 1221 (Bd. Pat. App. & Int. 1996) (copy attached). In *Reese*, the Examiner rejected claims directed to a genus of compounds for lack of enablement, relying on the same passage from *Dreshfield* cited by the Examiner in the present enablement rejection. *See id.* at page 2 of the attached copy. The Board found that the Examiner improperly applied *Dreshfield* to the facts in *Reese* because the *Dreshfield* passage pertained to a rejection on the grounds that the claims were "broader than appellant's original disclosure" and were not disclosed in the specification as originally filed. *See id.* at page 3. Although *Dreshfield* was decided before 35 U.S.C. § 112, first paragraph, was enacted, the Board concluded it was clear that *Dreshfield* "bears little relationship to the *enablement* provision of 35 U.S.C. § 112, first paragraph, but does bear relationship to the *description* provision of 35 U.S.C. § 112, first paragraph." *Id.* at page 3 (emphasis in original). As such, Applicants submit that the passage cited by the Examiner from *Dreshfield* is not applicable to the present enablement rejection.

The above notwithstanding, Applicants will address the passage from *Dreshfield* cited by the Examiner in the event the Examiner may find it applicable to the description provisions of 35 U.S.C. § 112, first paragraph. Applicants do not agree that the members of the 5-lipoxygenase inhibitor group "differ radically in their properties" in view of the detailed description and definitions above. Applicants assert that the specification provides a sufficient number of group members in accordance with *Dreshfield* in view of the numerous examples of members of the 5-lipoxygenase inhibitor group (*see, e.g.*, paragraphs [0017]-[0021]). In addition, Applicants assert that the specification provides that the group members are capable of accomplishing the desired results in accordance with *Dreshfield* in view of the above-mentioned disclosure related to 5-lipoxygenase inhibitors in the treatment of elevated serum triglycerides. As further evidence that the group members are capable of accomplishing the desired results, Applicants note that independent claim 1 specifies that the 5-lipoxygenase inhibitors are administered at "an effective amount being sufficient to reduce said elevated serum triglycerides." Therefore, the specification clearly supports the group of 5-lipoxygenase inhibitors in view of *Dreshfield*.

D. Data in support of the claimed methods for treating elevated serum triglycerides is available.

The Examiner, in explaining another aspect of the enablement rejection, emphasized that the examples "are drawn to the use of only one 5-lipoxygenase inhibitor for lowering serum triglycerides." Office Action at page 4. According to M.P.E.P. § 2164.02, Applicants wish to remind the Examiner that "[c]ompliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, does not turn on whether an

example is disclosed." However, as acknowledged by the Examiner at page 4 of the Office Action, the specification provides working examples using the BW 755c 5-lipoxygenase inhibitor. According to M.P.E.P. § 2164.02, where evidence is present for one member of a claimed genus, proof of enablement is required for the other members of the genus only where adequate reasons are advanced by the Examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation. Applicants have traversed the reasons advanced by the Examiner in the Office Action and have established that a person of ordinary skill in the art at the time of filing would have possessed the knowledge and skills necessary to make and use the subject matter of the present claims without undue experimentation. As such, in view of USPTO guidance, the working examples using the BW 755c 5-lipoxygenase inhibitor are sufficient support for the 5-lipoxygenase inhibitor genus of the claims.

For at least these reasons, the teaching in the art in conjunction with the disclosure in the specification indicate that a person of ordinary skill in the art at the time of filing would have possessed the knowledge and skills necessary to make and use the subject matter of the present claims. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the enablement rejection of claims 1, 4, 5, 8, 9 and 14-17.

E. Claim 8

The above notwithstanding, Applicants note that claim 8 depends from claim 1 and specifies that the 5-lipoxygenase inhibitor is a phenyl pyrazoline derivative. Therefore, claim 8 corresponds to the elected species of 5-lipoxygenase inhibitors that was previously examined. Applicants further note that the BW 755c compound in the

working examples is a phenyl pyrazoline derivative. *See, e.g.*, paragraph [0040] of the specification. In view these comments and the Examiner's comments regarding the enablement of the BW 755c compound (*see, e.g.*, pages 2 and 3 of the Office Action), Applicants respectfully submit that at least the elected species of phenyl pyrazoline derivatives specified in claim 8 is allowable. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the enablement rejection of at least claim 8.

F. Claim 9

The above notwithstanding, the Examiner indicated in the Office Action that the specification is "enabled for the treatment of elevated serum triglycerides using one 5-lipoxygenase inhibitor, BW755c." Office Action at page 3. Claim 9 depends from claim 1 and specifies that the 5-lipoxygenase inhibitor is 4,5-dihydro-1-(3-(trifluoromethyl)phenyl)-1H-pyrazol-3-amine (BW 755c). As such, it is Applicants' understanding that at least claim 9 falls within the scope of subject matter that the Examiner finds enabled by the specification. Accordingly, Applicants respectfully request that the enablement rejection of at least claim 9 be reconsidered and withdrawn.

III. First Supplemental Information Disclosure Statement

Applicants thank the Examiner for considering the documents cited in the Information Disclosure Statement filed March 15, 2004 and the Second Supplemental Information Disclosure Statement filed April 2, 2009. However, Applicants note that the Examiner has not provided an initialed copy of the Form PTO-1449 accompanying the First Supplemental Information Disclosure Statement filed June 22, 2004. Applicants

respectfully request that the Examiner return a copy of the initialed Form PTO-1449 to Applicants and indicate that the documents cited on the form have been considered.

Conclusion

The stated ground of rejection has been properly traversed. Applicants therefore respectfully request that the Examiner reconsider the presently outstanding rejection and that it be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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LEXSEE

Ex parte Reese

No. 94-1477

Board of Patent Appeals and Interferences

1996 Pat. App. LEXIS 10; 40 U.S.P.Q.2D (BNA) 1221

April 2, 1996, Decided

[*1]

Before Winters, William F. Smith, and Metz, administrative patent judges.

COUNSEL:

Jerry W. Berkstresser, of Shoemaker & Mattare, Arlington, Va., for appellant.

OPINIONBY: WINTERS

OPINION:

Winters, administrative patent judge.

This appeal was taken from the examiner's decision refusing to allow claims 18 and 24 through 33. Claims 20, 21 and 34, which are the only other claims remaining in the application, stand allowed. See the examiner's answer, page 1.

REPRESENTATIVE CLAIM

Claim 18, which is illustrative of the subject matter on appeal, reads as follows:

18. A protected compound of general formula:

[SEE ILLUSTRATION IN ORIGINAL]

wherein R <1> n1 represents C[1] - C[4] alkyl, R is the deoxy residue of a protected carbohydrate compound, R being different from R', and Ar is a monocyclic aryl group having an electron-withdrawing substituent which renders the group acid-labile.

[SEE ILLUSTRATION IN ORIGINAL]

n1 Application for patent filed September 14, 1988.

THE REFERENCES

In rejecting all of the appealed claims under *35 U.S.C. § 112,* first paragraph, the examiner relies on the following references:

Penco et al. (Penco)	4,604,381	Aug. 5, 1986
Myers et al. (Myers)	4,912,094	Mar. 27, 1990
Stober et al.	4,940,784	July 10, 1990

(Stober) Furneaux et al. (Furneaux) [*2]	5,047,518	Sept. 10, 1991

THE ISSUE

The issue presented for review is whether the examiner correctly rejected claims 18 and 24 through 33 under *35 U.S.C. § 112,* first paragraph, as based on a non-enabling disclosure.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification and all of the claims on appeal; (2) appellant's main brief and reply brief before the board and "APPLICANT'S RESPONSE TO EXAMINER'S RESPONSE TO REPLY BRIEF"; (3) the examiner's answer and response to reply brief and "RESPONSE TO APPELLANT'S RESPONSE TO REPLY BRIEF"; (4) the prior art references cited and relied on by the examiner.

On consideration of the record, including the above-listed materials, we *reverse* the rejection of claims 18 and 24 through 33 under *35 U.S.C. § 112,* first paragraph.

DISCUSSION

In rejecting all of the appealed claims under *35 U.S.C. § 112,* first paragraph, as based on a non-enabling disclosure, the examiner focuses on these claim recitations: (1) R is the deoxy residue of a protected carbohydrate compound; [*3] (2) R is the 2' deoxy residue of a protected ribonucleoside; and (3) Ar is a monocyclic aryl group having an electron-withdrawing substituent which renders appellant's protecting group acid-labile. In view of those recitations, the examiner argues, the scope of enablement provided in appellant's specification is not commensurate with the scope of protection sought to be patented. We disagree.

[1] Apparently, this rejection stems from the examiner's subjective belief that appellant's claims are "too broad" and that the specification requires more working examples. That subjective belief, however, is not adequately supported by evidence or sound scientific reasoning.

As stated in *In re Armbruster, 512 F.2d 676, 677-78, 185 USPQ 152, 153 (CCPA 1975),* quoting from *In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 369-70 (CCPA 1971):*

> It is incumbent upon the Patent Office, whenever a rejection on this basis [lack of enablement] is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence [*4] or reasoning which is inconsistent with the contested statement.

This the examiner has not done. In setting forth the statement of rejection in section (9) of the answer, the examiner (1) refers to the above-listed claim recitations; (2) argues that, in view of those recitations, the claims circumscribe a large area; (3) argues that more is required by way of working examples in the specification; and (4) argues that appellant does not provide "enumeration" of a sufficient number of compounds to support the relatively broad claims. That line of argument is long on opinion but short on evidence or sound scientific reasoning.

The examiner relies heavily on this passage from *In re Dreshfield, 110 F.2d 235, 240, 45 USPQ 36, 41 (CCPA 1940):*

> It is well settled that in cases involving chemicals and chemical compounds which differ radically in their properties it must appear in an applicant's specification "either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that 'the chemicals or chemical combinations'" included in the claims are capable of accomplishing the desired result. [*5] [citation omitted]

See the examiner's answer, section (9). We find it clear, however, that the examiner lifts that passage out of context from the pre-1952 *Dreshfield* opinion and attempts, improperly, to inject the same in a discussion centering on the enablement provision of *35 U.S.C. § 112,* first paragraph. Careful review of the *Dreshfield* opinion reveals that the above-noted passage supports the court's holding that

> claims 15, 16, and 17 were properly rejected by the Primary Examiner on the ground that they are *broader than appellant's original disclosure* [emphasis added].

See *In re Dreshfield, 110 F.2d at 240, 45 USPQ at 41.* According to the court, those claims include compounds not disclosed in the specification as originally filed. Although *35 U.S.C. § 112,* first paragraph, was enacted well after *Dreshfield* was decided, nonetheless, it appears that the above-noted passage from *Dreshfield* bears little relationship to the *enablement* provision of *35 U.S.C. § 112,* first paragraph, but does [*6] bear relationship to the *description* provision of *35 U.S.C. § 112,* first paragraph. For these reasons, the examiner's reliance on *Dreshfield* is misplaced. The examiner was remiss in not following more recent case law providing guidance on the shifting burdens of persuasion in connection with a rejection under the enablement provision of *35 U.S.C. § 112,* first paragraph.

In section (10) of the answer, entitled "Response to Argument", the examiner belatedly discusses the factors listed in *Ex parte Forman, 230 USPQ 546, 547* (Bd. Pat. App. & Int. 1986) pertaining to the issue of undue experimentation. According to the examiner, appellant's specification does not contain a sufficiently explicit disclosure which would enable a person having ordinary skill in the art to practice the claimed invention without the exercise of undue experimentation. As repeatedly pointed out by appellant in his reply brief, however, the examiner sets forth his conclusions and opinions unsupported by facts. Where, as here, the examiner's "Response to Argument" is not supported by evidence, facts, or [*7] sound scientific reasoning, we find that the examiner has not established a *prima facie* case of lack of enablement under *35 U.S.C. § 112,* first paragraph.

The examiner's decision is *reversed.*

REVERSED.

ILLUSTRATION 1, no caption; ILLUSTRATION 2, no caption

Legal Topics:

For related research and practice materials, see the following legal topics:
Patent LawClaims & SpecificationsClaim LanguageGeneral OverviewPatent LawClaims & SpecificationsDescription RequirementGeneral OverviewPatent LawU.S. Patent & Trademark Office ProceedingsGeneral Overview